

CLAIMS

1. A primary package containing an aqueous solution for parenteral administration
5 comprising a low molecular weight peptide-based thrombin inhibitor or a salt thereof,
having a pH in the range 3 to 8, the primary package being sealed with a rubber stopper or
plunger containing bromobutyl rubber.
2. A primary package according to claim 1, wherein the primary package is a vial.
- 10 3. A primary package according to claim 1, wherein the primary package is a bottle.
4. A primary package according to claim 1, wherein the primary package is a cartridge.
- 15 5. A primary package according to claim 1, wherein the primary package is a prefilled
syringe.
6. A primary package according to any of the preceding claims, wherein the solution is a
NaCl solution.
- 20 7. A primary package according to any of the preceding claims, wherein the solution also
comprises hydroxy-propyl- β -cyclodextrin.
8. A primary package according to any of the preceding claims, wherein the concentration
25 of the thrombin inhibitor in the solution is in the range 0.001-100 mg/ml, preferably 2.5-20
mg/ml.
9. A primary package according to any of the preceding claims, wherein the pH of the
solution is in the range 3-8.

10. A primary package according to claim 9, wherein the pH of the solution is about 5.
11. A primary package according to any of the preceding claims, wherein the thrombin inhibitor is melagatran.
- 5 12. A primary package according to any of the preceding claims, wherein the thrombin inhibitor in the solution is inogatran.
13. A primary package according to any of the preceding claims, wherein the thrombin
10 inhibitor in the solution is compound A.
14. A primary package according to any of the preceding claims, wherein the bromobutyl rubber material consists of, or correspond to, the quality PH 4023/53.
- 15 15. A primary package according to any of claims 1-13, wherein the bromobutyl rubber material consists of, or correspond to, the quality W 4416/50.
16. A primary package according to any of claims 1-13, wherein the bromobutyl rubber material consists of, or correspond to, the quality FM 257.
- 20 17. Use of a rubber stopper or plunger containing bromobutyl rubber for sealing a primary package, such as a vial, a bottle, a cartridge or a prefilled syringe, containing a low molecular weight peptide-based thrombin inhibitor in an aqueous solution.
- 25 18. A process for the manufacture of a primary package according to claim 1 comprising the steps of dissolving a low molecular weight peptide-based thrombin inhibitor in an aqueous solution, adjusting the pH of the solution to be in the range 3 to 8, optionally adding a cyclodextrin substance, sterile filtering the solution and filling it on a primary package which is then sealed with a rubber stopper or plunger containing
30 bromobutyl rubber.